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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,194	06/02/2006	Johannes Bartholomaus	512100-2057	3326

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,194	BARTHOLOMAUS, JOHANNES	
	Examiner	Art Unit	
	GINA C. YU	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 14, 2010 has been entered.

The previous claim rejections indicated in the Office action dated April 13, 2010 are withdrawn in view of the claim amendment submitted on June 14, 2010.

Claim Objections

Claims 3 and 16 are objected to because of the following informalities: Claims 3 and 16 are duplicates. Appropriate correction is required.

Claim Rejections - 35 USC § 103 (New)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rupprecht et al. (US 6780504 B2) ("Rupprecht") in view of Becher (US 6153222) and Zerbe et al. (US 6177096 B1) ("Zerbe").

Rupprecht discloses a dosage form in a multi-layered film which contains an active ingredient, wherein the dosage form comprises a cover layer, at least one active ingredient-containing layer and an adhesive layer. See col. 1, line 53 - 067; instant claims 1, 9, 10, 18. Example 2 discloses such multi-layer film comprising 1 wt % prednisolone. The active ingredient-containing layer is formed from in-situ crosslinking of hydroxypropylmethylcellulose (MHPC), and tannin (a cross-linker) in water in presence of prednisolone. See Example 2, (b); see also Example 1; instant claims 1, 3, 5, 7, 16, 17. Rupprecht discloses to optimize the film properties by adjusting the ratio of polymer to crosslinking agent to from 1:1 to 4:1. See col. 3, lines 1-22; instant claim 21. The reference further teaches that the prior art multi-layer film dosage form allows the active ingredient to distribute uniformly over the whole layer, and that the active ingredient-containing layer exhibits horizontal and/or vertical gradients of the respective active ingredient. See col. 3, lines 51 – 67; instant claims 11 and 19.

The active ingredients suitable for application of the prior art dosage film form include nutrients, analgesics, antiallergic agents, antibiotics, antiemetics, antiseptics, antihistamines, antihypertensive agents, appetite suppressants, cardiac remedies, chemotherapeutic agents, enzymes, hormones, immunomodulators, inoculations, local anesthetics, psychoactive drugs, spasmolytics, virustatics, vitamins, cytostatics, plant protection agent, growth promoter and/or fertilizer. See col. 4, lines 1-13; instant claims 7 and 8. Rupprecht teaches the prior art film is suitable in particular for use as a transmuosal medicament. See col. 8, lines 12 – 14; instant claim 15. Further including

an additional barrier layer to the release side of the film to protect the release of the active agent is also taught. See col. 8, bridging par.; instant claims 13.

Rupprecht fails to teach adding glycerol in the active ingredient-containing layer of the film dosage form.

Becher teaches a dosage form in film of oral application, comprising a mixture of active ingredient, film former, and softeners. See abstract. The reference teaches using crosslinked carboxyvinyl copolymers and/or crosslinked polyvinyl pyrrolidone as film formers. See col. 2, lines 9-12. The reference teaches polyethylene glycol or glycerol as the softener. See Further substances. The film is supplied with release paper attached thereon, meeting the instant claims 9, 13, and 18.

Becher fails to teach the amount of glycerol as based on the total amount of crosslinked hydrophilic polymers.

Zerbe teaches a film containing therapeutic agents and/or breath freshening agent for use in the oral cavity. See instant claims 5 and 6. The film comprises water-soluble polymers selected from water-soluble cellulose derivatives and polyacrylates, among others. The reference teaches the film also contains one or more plasticizers. Example 1 teaches a dosage form in film form obtained from a composition comprising 6 g of glycerol and 30 g of hydroxypropylmethyl cellulose (20% of glycerol based on the total amount of the hydrophilic polymer). See instant claims 1 and 3. The suitable pharmaceutical actives for the oral dosage forms include psychoactive drugs, antihistamines, hormones, antibiotics, and chemotherapeutics. See col. 3, lines 16 – 33.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teachings of Rupprecht by employing glycerol as a softener or plasticizer for the film as motivated by Becher and Zerbe. The skilled artisan would have been motivated to do so because 1) Becher teaches dosage forms in film forms that utilize glycerol as a plasticizer and 2) Zerbe discloses the weight amount of glycerol used per the weight amount of film-forming polymers used in a similar formulations. Since Becher teaches adding glycerol with crosslinked film forming polymers, the skilled artisan would have had a reasonable expectation of successfully producing a stable film dosage form with improved and softened film properties.

Claim 1 requires the weight range of glycerol to from 30 % to 60 % by weight based on the total amount of crosslinked hydrophilic polymers. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, the utility of a plasticizer as a film softener is taught by Becher and Zerbe, and the latter teaches an operative weight amount of glycerol as plasticizer in a composition comprising a film forming polymer. Discovering by routine experimentations an optimal weight amount of the plasticizer for a different type of polymer such as the crosslinked hydrophilic polymer of Becher would take no more than ordinary skill of the art.

Claims 1, 3, 5-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rupprecht in view of Becher and Lydzinski et al. (US 2003/0099692).

Rupprecht and Becher are relied upon as discussed above.

Becher fails to teach the amount of the plasticizer.

Lydzinski teaches a dosage form in film form for delivering a variety of agents to a substrate, wherein the active agents may be pharmaceuticals such as dentifrice, antiseptics or agricultural agent such as fertilizers. See [0024]; Instant claims 6-8. The reference teaches plasticizers such as polyols, particularly glycerine, is used in "any desired amount" to increase the apparent flexibility of the film, although the prior art mentions using the plasticizer up to about 15 percent by weight of starch component which forms the bases for the prior art film form. See [0026].

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teachings of Rupprecht by employing glycerol as a softener or plasticizer for the film as motivated by Becher and Lydzinski. The skilled artisan would have been motivated to do so because 1) Becher teaches dosage forms in film that utilize glycerol as a plasticizer and 2) Lydzinski discloses the specific weight amount of glycerol used per the weight amount of film-forming polymers used in a similar formulations. Since Becher teaches adding glycerol with crosslinked film forming polymers, the skilled artisan would have had a reasonable expectation of successfully producing a stable film dosage form with improved and softened film properties.

With respect to the weight amount of the plasticizer, since Lydzinski teaches plasticizers are used in any desired amount and to increase flexibility of the film, the

skilled artisan would have been obviously motivated to find an optimal weight amount of the plasticizer to obtain the desired level of flexibility. Doing so by routine experimentations would have been well within the skill of the art according to the teachings and suggestions of the references.

Response to Arguments

Applicant's arguments filed on June 14, 2010 have been fully considered but they are not moot in view of the new grounds of rejection in part, and unpersuasive in part.

Applicant's arguments with respect to the claim limitation "in-situ" crosslinking polymers are moot in view of the new grounds of rejection based on the Rupprecht reference.

Applicant has stated that the previous obviousness rejections based on the combined teachings of Becher/Zerbe and those of Becher/Lydzinski are "duplicate rejections". Examiner respectfully disagrees with the remarks. Zerbe and Lydzinski are both directed to dosage forms in films comprising glycerol as a film softener, however, these references each provide different teachings. As indicated above, Zerbe teaches using 20wt % of glycerin while Lydzinski teaches using the same plasticizer in an amount of 15 wt % and further teaches to increase the amount to improve the flexibility of the film. The fact that ***multiple*** prior arts teach using glycerin to produce flexible films supports the examiner's position that person of ordinary skill in the art was well aware of such technology. However, the different details of the references independently support two separate prima facie cases of obviousness of the present invention as indicated above.

Examiner also disagrees with applicant's remarks that Lydzinski is a "weaker reference", as the reference provides specific reasons and motivations for a skilled artisan to increase the amount of glycerin and produce more flexible film.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydown G. Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GINA C. YU/
Primary Examiner, Art Unit 1617